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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,841	YOUNG ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/11/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-47,50-52 and 54-58* is/are rejected.

7)☒ Claim(s) *48, 53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 39-58 are pending and under consideration.

Response to Amendment

The rejection of claims 39-40 under 35 USC 101 has been obviated by Applicant's amendment and is thus withdrawn.

Claims 39, 41, 43 stand rejected under 35 U.S.C. 102(b) as being anticipated by Christie et al. (1989).

Claims 39-44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tamkun et al. (1991).

Claims 40, 42, 44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Leicher et al. (1996).

New and remaining issues are set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 43-44stand rejected, and new claims 55, 58 are rejected, under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 43-44, 55, 58 as written are directed to host cells comprising a polynucleotide. Since these claims do not contain a limitation wherein the host cells are isolated, the claims read on a transgenic human, which is not patentable subject matter. This rejection could be obviated by addition of a limitation wherein the host cell is isolated.

Applicant argues that the claims are directed to genetically engineered cells, and that the fact that the cells can be included in a human body does not render the claimed cell non-statutory. However, the issue is not that the cells could be implanted in a human body, as this would not render them non-statutory, but that the claims read on cells in a human that are the product of in vivo transfection (e.g. as a result of gene therapy), and also encompass a human that would result from e.g. somatic cell nuclear transfer of a transfected cell comprising the polynucleotide, and encompasses the whole human. This would not be statutory subject matter. Applicant draws the analogy that drugs and medical implants are patentable despite being present in a human, but this analogy is inapposite. The claims as written encompass the cells in the human that comprise the polynucleotide, which is possibly every cell in the human, whereas the drugs and medical implants, while present in a body, would not be encompassed by the product claims directed to the drug or medical device.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-44 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, which is enabling for a full-length polynucleotide sequence of SEQ ID NO: 3, 4, 7, 8; and a polynucleotide sequence 90% identical to SEQ ID NO: 3, 4, 7, 8 wherein the encoded polypeptide which binds to an amino-terminal inactivation region of hKvβ1 protein, or the intracellular receptor region of an α-subunit of a hKv1.1 protein, does not reasonably provide enablement for a polynucleotide sequence 90% identical to SEQ ID NO: 3, 4, 7, 8 wherein the encoded polypeptide which binds to an amino-terminal inactivation region of an ion channel

protein, or the intracellular receptor region of an α-subunit of a voltage-gated ion channel, for reasons of record set forth in the Office Action of 8/11/2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection of record set forth that the claims are drawn to polynucleotide sequences that are 90% identical to sequences as set forth in the specification. The claims are overly broad since insufficient guidance is provided as to which of the myriad of variant nucleic acids encode polypeptides which will retain the characteristics of SEQ ID NO: 3, 4, 7, 8. Applicant argues that using the specification as a guide, coupled with what is known in the art, one of ordinary skill in the art could readily prepare variants that would reflect the activities and/or features characteristic of the polypeptides, such as biological activity and other characteristics that are described in the specification. While the claims set forth a functional limitation for the encoded variant polypeptides wherein the encoded polypeptide binds to an amino-terminal inactivation region of an ion channel protein, or the intracellular receptor region of an α-subunit of a voltage-gated ion channel, however, the Specification only teaches proteins which binds to an amino-terminal inactivation region of hKvβ1 protein, or the intracellular receptor region of an α-subunit of a hKv1.1 protein. The term ion channel and alpha-subunit of a voltage gated ion channel as set forth for the target of the binding activity, are insufficient to direct the skilled artisan to the function which the encoded variant polypeptide must possess. The skilled artisan would not be apprised of the metes and bounds of the functional limitation with regard to binding activity. Since detailed information regarding the structural and functional requirements of the encoded polypeptide is lacking, it is unpredictable as to which variations, if any, meet the limitations of

the claims. Applicant further argues that despite the lack of working, in view of the availability of appropriate literature and software tools, as well as the level of guidance provided in the specification, one of ordinary skill in the art would be able to design and produce a variant comprising a desired mutation yet retaining binding activity. However, Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass methods using polypeptides which the specification only teaches one skilled in the art to test for functional variants to be used in the claimed method. It would require undue experimentation for one of skill in the art to make and use the claimed polynucleotides, since the skilled artisan would have to first make polynucleotides encoding polypeptide variants of the encoded polypeptides, then test for function. Because the amino acid sequence of a polypeptide determines its structural and functional properties, and predictability of which amino acids can be substituted is extremely complex, accurate predictions of a polypeptide's structure from mere sequence data are limited. Thus, since Applicant has only taught how to test for encoded polypeptide variants, and has not taught how to make polynucleotides encoding polypeptide variants, it would require undue experimentation of one of skill in the art to make and use the claimed polynucleotides.

Claims 39-44 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office Action of 8/11/2004. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The rejection of record set forth that these are genus claims. The claims are drawn to polynucleotide sequences that are 90% identical to sequences as set forth in the specification. Applicant argues that the specification provides exemplary methods for determining sequence identities. However, the term ion channel and alpha-subunit of a voltage gated ion channel as set forth for the target of the binding activity, are insufficient to direct the skilled artisan to the function which the encoded variant polypeptide must possess. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient correlation between structural and function al properties. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated

and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed: there is no guidance in the art as to what the defining characteristics of the polypeptides might be. Thus, no identifying characteristics or properties of the instant polynucleotides encoding polypeptides are provided such that one of skill would be able to predictably identify the molecules that would retain binding activity of the encoded polypeptides.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45-47, 49-52, 54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,856,155 (Li).

The claims are drawn to a polynucleotide encoding a fusion protein comprising an S4-S5 cytoplasmic loop of an ion channel and a DNA-binding or transcription activation domain of a transcriptional activator, wherein the S4-S5 region is from a potassium channel alpha-subunit. The '155 patent discloses a yeast two-hybrid system. The system comprises a first vector containing nucleic acid sequences encoding a fusion protein of a DNA binding domain and a polypeptide consisting of the NAB and linking region of an alpha-subunit of a Shaker-like

potassium ion channel, and a second vector containing nucleic acid sequences encoding a fusion protein of a transactivation domain and a polypeptide consisting of the NAB and linking region of an alpha-subunit of a Shaker-like potassium ion channel (column 4, lines 10-25). The alpha subunit is disclosed as being Kv1.4 (column 23, lines 10-25).

Conclusion

Claims 39-47, 50-52, 54-58 are rejected.

Claims 48, 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

References

The Office will no longer be supplying paper copies of U.S. Patents cited in Office Actions. Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Applicant may direct inquiries about the use of the Office's PAIR system to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
January 19, 2005

JOSEPH MURPHY
PATENT EXAMINER